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Guidelines on the Acceptance of Existing Test Data

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Abstract
Environmental Technology Verification (ETV) is a new tool enabling the verification of the performance claims put forward by developers of innovative environmental technologies. The EU-ETV programme, launched in 2011 by DG-ENV, is supported by Technical Working Groups (TWGs), one for each technology area active under the Pilot programme. These TWGs are chaired by the JRC and composed by Commission Invited Experts and by Experts representing the Verification Bodies (VBs) with the overall aim to harmonise and exchange good practices.

The present document clarifies and provides guidance to help Verification Bodies to evaluate existing data and to determine whether it meets the requirements set out in the EU-ETV Global verification Protocol (GVP). Existing data refers to data that have been produced prior to a verification, before that the VB establishes the Specific Verification Protocol.

This document, adopted on the on the 07/06/2016 by the TWGs, is a guidance document, with the meaning given in the General Verification Protocol of the EU ETV pilot programme (version 1.2), Section A.II.4.3. It has been produced by the EU ETV Technical Working Groups, chaired by the JRC, under the auspices of DG Environment.
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Contents

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[1] We also thank experts who have contributed to the document but have left the Technical Working Groups before the approval.

1 Introduction

1.1 The EU ETV Pilot Programme

Environmental Technology Verification (ETV) is a tool to help innovative environmental technologies to reach the market. It consists of the validation of the performance claims put forward by technology manufacturers, on a voluntary basis, by qualified third parties. This should help manufacturers prove the reliability of their claims, and help technology purchasers identify innovations that suit their needs. This is particularly relevant in a context where there are no available standards or labels applicable to the technology. As a result, technological lock-in is overcome while more effective and cheaper environmental protection measures can emerge.

The EU ETV pilot programme, run by the European Commission, is implemented by Verification Bodies (VBs) specifically accredited for ETV. The reference defining ETV procedures and requirements is the General Verification Protocol (GVP). It ensures that all verifications follow the same process and have the same value. VBs are coordinated by Technical Working Groups, providing guidance on the implementation of ETV and ensuring the adequate harmonisation of practices.

1.2 Existing test data in the context of EU-ETV

Under the EU ETV, verifications require a "*defendable and complete data set*" (B.VI.4) produced through testing. The Verification Body establishes a Specific Verification Protocol (SVP) that determines which parameters have to be measured and sets out the requirements on test design and data quality, as well as on evaluation methods and quality assurance.

Two possibilities exist:

1. the tests are carried out during verification, based on the requirements of the SVP

2. the proposer may already possess some test data before the verification is initiated. The GVP explicitly includes specific clauses allowing the inclusion of such 'existing data' in the verification process, provided that they meet a series of requirements including compliance with the SVP requirements. The Verification Body assesses these data, and reports on their acceptability in a dedicated section of the SVP.

In the GVP, the main requirements for existing data are defined in sections B.IV.5 "Assessment of existing data" and "C.II Quality control for existing data". The purpose of this document is to present and discuss these requirements, along with providing guidance on how to apply them in practice, in a harmonised and reasoned manner.

2 Evaluation of existing test data streamlined in the ETV Process

The ETV process is subdivided in a series of steps. Existing data have to be considered in most of them. The sequence is summarised in the figure below and described in the following paragraphs.

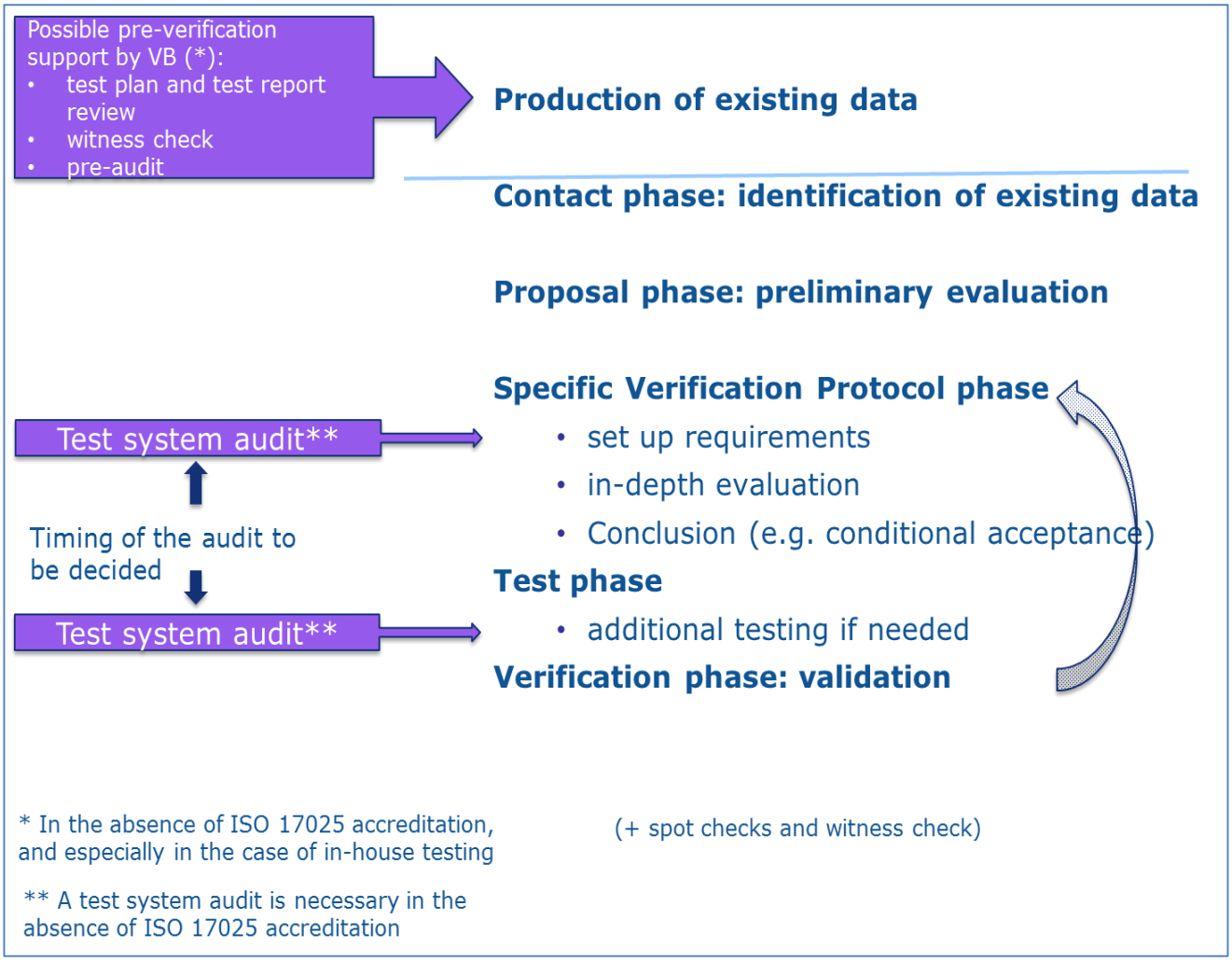

Figure 1: Existing data in the ETV Process

2.1 Contact phase: identification of existing data

The aim of the contact phase (quickscan) is to "*enable the Verification Body to assess the eligibility of the technology and to give an early indication of the complexity and potential range of costs of a full verification*" (GVP B.II.1). The cost and the complexity of the verification may be influenced by the existence of relevant test data[2]. Therefore, it is important to clarify at this stage if there are any existing data relevant to the performance claim and to have some preliminary idea if this data will meet the requirements of the GVP.

In the Quickscan, the proposer is asked the following question:

> "*Are there available test results or other data to back-up the technology's performance* (yes/no)?"

[2] On the one hand the availability of valid existing data may reduce future testing needs and related expenses. But on the other hand, experience indicates that from a VB's perspective it may be more complex and costly to analyse existing data - for which the QA documentation might be scattered and hard to interpret - than new data obtained in the framework of the QA system of the GVP. This is especially true when this data have not been produced by an accredited Test Body.

with an accompanying remark:

> "*Please include in your comments, if a test plan was followed, if standard methods were used, if testing was done by accredited testing bodies, i.e. ISO 17025*."

At this stage, the proposer is not requested to provide the actual data; he just needs to answer the question.

In the assessment of the quickscan, the VB has to answer the following questions and to provide comments as appropriate:

- "Test results are available (yes/no)"
- "Further testing would/could be necessary (yes/no)"

It is important to stress that at this stage, the VB is not expected to perform an in-depth review of the existing data. Such in-depth review must take place at a later stage and be based on the Specific Verification Protocol (SVP), that establishes how the verification and testing have to be conducted. Therefore any indication given by the VB at this stage is indicative only. Great care is thus advised when answering "no" to the question "*Further testing would/could be necessary (yes/no)*". It is recommended to add a comment, e.g. "*no, unless the outcome of the detailed evaluation of the data is negative"* or to answer "yes" and add "*unless evaluation of existing data proves that data are acceptable and sufficient to support the performance claim*"

2.2 Proposal phase: preliminary evaluation

The aim of the proposal is to provide all relevant information needed to conduct the ETV process. In the proposal, the proposer is asked *inter alia* to provide all details regarding the existing data including test plans, test reports, test methods and the qualifications of the test bodies. To facilitate the evaluation by the VB, the proposer has to answer the following questions provided for in the proposal form:

Are there available test results or other data to back-up the technology's performance?

☐ Yes

Description of test plan:

Description of test methods, including reference if standard methods were used:

Description of existing data:

Qualification of the test body for the relevant tests:

☐ ISO 17025 ☐ none ☐ other:

☐ No

Is there a test plan available? ☐ Yes ☐ No ☐ Unknown

Is there a test method available? ☐ Yes ☐ No ☐ Unknown

Full description:

The VB will comment on the acceptability of this existing data, in the section "*Assessment of existing data*" of the 'Proposal' form. This is facilitated by a checklist included in the proposal form. A positive answer by the VB to all the questions is needed in order to consider the existing data as acceptable at this stage:

Question (yes/no)	Minimal requirement	Comments
Tests performed on technology?	Tests have been performed on the technology presented for verification.	The data should come from tests (not input/output calculations for example) and the item tested and intended application should be the same as the technology presented for verification.
Test body suitably qualified?	See below, section 3.1.	The test body can also be the Proposer An audit has to be performed in the absence of EN ISO 17025 accreditation for the relevant test methods
Test plan available?	Test plan must be available.	
Test plan suitable?	The documents provided must cover in substance the content provided in Appendix 7 of GVP 'Table of content for the test plan and test report'.	At the proposal stage the judgement should focus on the conformity of the test plan content with the requirements of the GVP specified in Appendix 7 only. If these requirements are met a conditional acceptance of the data can be assumed with a condition "*Provided the test plan meets the requirements of the Specific Verification Protocol*"
Test method available (standards)?	Must be available.	It is expected that the test plan will describe the test method or will refer to a test method described elsewhere (e.g. a standard or other document). The suitability of the test method is again conditional to its accordance with the relevant requirements in the Specific Verification Protocol to be established. A careful judgement is thus required here.
Test methods described?	Must be described.	
Test methods suitable?	To be based on best judgement of the VB. If the description of the test method does not allow judging its accuracy and reproducibility it may be a reason for rejecting it.	
Test methods reproducible?		

Test methods accurate?		
Test results available?	The documents provided must cover in substance the content provided in Appendix 7 of GVP 'Table of content for the test plan and test report'. Proposer must be able to provide the raw data for future review by the VB.	
Test results relevant to the performance claim?	To be based on judgement of the VB.	This can include: relevance of the test data to verify the claimed performance of (i.e. performance parameters to be verified), the precision of the results and their statistical validity, the extent to which the results actually support the claim etc.
Test results can be used in the verification process	Answers to all the above is positive.	This can only be a preliminary judgement subject to meeting the requirements in the Specific Verification Protocol.

The conclusion reached at this stage is a preliminary judgement that will help to enable initial assessment of costs, draft the time schedule of the verification, provide feedback for the development of the test design in the SVP, and sometimes to modify the claim. However it is very clear from the GVP that meeting "*the applicable requirements set in the specific verification protocol*" is an essential acceptation criterion for accepting the existing data (GVP C.II). Therefore a firm judgement on the acceptance of the existing test data for the purpose of verification can only be made in the next step (Specific Verification Protocol phase).

2.3 Specific Verification Protocol phase: in-depth evaluation

Once the contract with the proposer is signed, the next step in the verification process is the establishment of the Specific Verification Protocol by the Verification Body. The SVP specifies which parameters to include in the verification and sets out the requirements on test design and data quality, as well as on evaluation methods. Once this is established, then the VB is in a position to assess the existing data.

The GVP requirements related to existing data are described below in section 3. In particular, the GVP specifies that:

> "*The Verification Body shall assess the existing test data against the parameters, methods, quality requirements and target values defined for this specific verification in application of B.IV.3 and B.IV.4.*" (B.IV.5), and
>
> "*The quality of the existing data shall be evaluated by the Verification Body, by checking documentation, raw data and quality control data from the data production*." (C.II)

This indicates that the assessment of existing data shall be done against: performance parameters specified for verification, the test methods as well as the quality management. Chapters B.IV.2 (Definition of verification parameters) and B .IV.3 (Requirements on test design and test methods) of the GVP and the corresponding sections of the Specific Verification Protocol shall be used for this assessment. The assessment shall also consider the relevant GVP requirements as explained further in section 3 below (which may require the execution of a test system audit). How to perform this assessment is further described in sections 3 and 4 below.

The result of this in-depth evaluation (e.g. which data can be (conditionally) accepted, and which data cannot) is to be reported in the chapter 6 of the Specific Verification Protocol. There are two

issues to be assessed: whether the existing data can be accepted (conditionally or not) and whether it is sufficient to support the claim.

The GVP further states (C.II):

> *"In addition to checking documentation and data, the Verification Body may undertake one or more of the following actions to evaluate the acceptability of the existing data, in particular in the absence of accreditation or in the case of data produced by the proposer or by bodies dependent upon the proposer:*
>
> - *spot checks;*
> - *witness checks;*
> - *conditional acceptance of existing data, in which case the conditions for acceptance shall be detailed in the specific verification protocol; these conditions may include re-testing.*
>
> *Spot checks and witness checks may be performed before finalisation of the specific verification protocol; otherwise they need to be combined with a conditional acceptance."*

These actions should be, insofar as possible, foreseen and included in the contract at the proposal stage. If this was not possible at the proposal stage, the proposer should be duly informed at the specific verification protocol stage and, if appropriate, the contract should be amended to take account of these actions.

All these actions are further discussed in section 4.

2.4 Verification phase: validation

At the end of the verification process, the VB will prepare the verification report, which covers the assessment of <u>all test data</u> (existing and new). The GVP states the following:

> *"The Verification Body then assesses whether these collected data are complete and satisfy the requirements and criteria for acceptance provided in the specific verification protocol and test plan. Special attention is paid to the determination of the associated uncertainty. The verification body shall also carry out a critical review of the data, e.g. through random consistency checks."* (B.VI.3)
>
> *[…] "Based on the previous steps[3], the Verification Body shall conclude whether there is a defendable and complete data set for verification and reporting. <u>If this is not the case, previous steps of the verification procedure, including the specific verification protocol, assessment of existing data and testing phase, may have to be re-iterated.</u>*
>
> *When the Verification Body reaches a positive conclusion, it shall report this assessment as part of the verification report."* (B.VI.4)

[3] Test report review, Conclusion of the test system assessment, and Assessment of data

The underlined sentence highlights the fact that test results obtained during verification may lead to a re-assessment of the validity of existing data, for example if new data are in contradiction with the existing data. Such situation could arise especially when conditional acceptance has been foreseen. It may eventually be necessary to perform additional testing in order to replace the discarded existing data.

The final assessment of existing data based on relevant findings gathered during the verification phase is to be reported in section 3.1 of the Verification report and of the Statement of Verification.

Note: Existing data that is not accepted for the purpose of verification may be used for other purposes as background information. For instance it could provide useful information for test design (e.g. the standard deviations computed form the data may provide indication concerning the size and number of samples needed). Some information could also be provided as 'additional information' in the statement of verification (with the relevant caveats).

3 GVP requirements related to existing data

Most of the GVP requirements related to existing data are spelled out in the GVP sections 'B.IV.6 Assessment of existing data' and 'C.II Quality control for existing data'. These requirements are discussed below.

3.1 Quality requirements and qualifications of the test body

The body that performed the tests or analyses has to be competent and qualified for doing so.

The GVP states that:

> *"In order to facilitate the acceptability of the existing test data, it is recommended that tests carried out before an ETV proposal are performed by organisations accredited as complying with the requirements of ISO/IEC 17025 for the relevant test methods."* (B.IV.5).

Compliance with this recommendation would greatly simplify the verification procedure, because in the absence of such accreditation, the VB will have to evaluate the suitability of the test body's Quality Management System (QMS) and test system at the moment of testing, as indicated below.

As for new data, the GVP distinguishes two situations: tests and tests that can be considered as analyses. The GVP clarifies the difference between the two:

> *"Analyses are distinguished from tests when they follow highly standardized methods, independent of the innovation or specific features of the technology at the origin of the test samples. This concerns for example biological or chemical analysis of water samples and other products."* (A.II.6.1)

The minimal qualifications for test bodies are presented and discussed below. If the body does not comply with the requirements below, the existing data are not considered acceptable.

The GVP states that:

> *"The existing data shall be accepted only if it has been produced and reported under quality assurance compliant with the relevant quality management and general test requirements, as indicated in A.II.6.1 and C.I. In the event that the body producing these data was accredited according to ISO/IEC 17025, for the relevant methods of testing and calibration at the time of production of these data, it shall be presumed to comply with these requirements."* (C.II)
>
> *"The quality management and general test requirements of the GVP are those requirements of ISO/IEC Standard 17025 – 'General requirements for the competence of testing and calibration laboratories', that are considered relevant for the tests to be performed. The Verification Body is responsible for deciding which requirements of ISO/IEC 17025 are relevant and these shall be clearly indicated in the specific verification protocol established for the technology to be tested, in application of Chapter B.IV. A list of requirements that need to be considered is provided in Appendix 10.*
>
> *[…]*
>
> *Moreover, if tests consist of analyses, the test body performing those analyses shall be accredited to applying ISO/IEC 17025 for the relevant analytical methods. Routine analytical quality control data and participation in proficiency tests for the analysis used and the relevant period shall be made available to the Verification Body upon request.*
>
> *The Verification Body shall control the fulfilment of all requirements of the GVP including the quality management and general test requirements, through a test system assessment in accordance with Part C, including a test system audit where applicable"* (A.II.6.1)

The VB has to assess whether the quality management and general test requirements of the GVP were met at the moment of the testing. This is similar to the assessment that a VB performs for new data. This evaluation is done through the "test system assessment". Without an ISO/IEC 17025 accreditation valid at the moment of the testing covering the tests under consideration, then test system assessment has to include a "test system audit". The main difference with new data is that, in the case of existing data, the VB has to consider the situation at the moment of testing and not the current one, which can make things more complicated and uncertain. The test system audit is further discussed in section 3.5 below, and is described in a separate guidance document.

The involvement of a verification body before production of existing data may prove useful for test bodies that are not ISO/IEC 17025 accredited for the relevant test methods, for example to perform an anticipative test system audit (see separate guidance document on auditing of test bodies);

3.2 In-House testing

The proposer can also act as test body by performing the tests in-house. In such situation, the GVP specifies that:

> "*In the case where the proposer performs the necessary tests in-house, in accordance with the provisions of Chapter B.V, the proposer shall fulfil the requirements described above*

> *for test bodies and this is to be controlled by the Verification Body in the same way."* (A.II.6.1)

This implies that the requirements presented in the previous section (3.1) also apply to a proposer performing in-house testing. Moreover, in the case of new data, GVP section B.V specifies that for in-house testing:

> *" [...] the test plans, all preparatory measures such as sampling and the actual tests shall be prepared and implemented by the proposer in agreement with, and where appropriate witnessed by, the Verification Body."*

In the case of existing data produced in-house, the presence of an independent and competent witness during testing is also considered essential[4]. This shall be proven by a written report in which the witness spells out his findings[5].

Moreover the involvement of a test body or a verification body may prove useful to the proposer, for example to:

- Carry out an anticipative test system audit (see separate guidance document on auditing of test bodies);
- Draft the test plans or review the test plans drafted by the proposer;
- Witness testing done by the proposer, where appropriate;
- Review the test report drafted by the proposer.

3.3 Required documentation

The existing data must be backed by all the necessary documentation to assess its validity, as already indicated in section 2.2. For example, in the case of ISO 17025 accreditation, a proof shall be supplied. More specifically the GVP says:

> "The existing test data *"shall include sufficient information for assessment, i.e. in addition to the data itself, full address and status (e.g. independent/dependent, certifications and accreditations etc.) of the data supplier and of any third parties involved (e.g. test design, witnesses etc.). Data must be supplied in a format that allows assessment against the requirements as set in B.IV.3 [Requirements on test design and data quality]"* (B.IV.5)

The GVP also specifies that:

> *"The test plan and test report shall be provided along with any other information covering in substance the content provided in Appendix 7 'Table of content for the test plan and test report' ".* (B.IV.5)

[4] Unless proof is provided that tests are carried out by an independent entity within the proposer, and that the personnel involved are free from any undue commercial, financial and other pressures which might influence their technical judgement.

[5] This report should indicate at least place and date of tests, which test and QA procedures have been followed, which technology model has been tested, and note any deviation.

This means that the documentation has to cover topics like qualification of the personnel who performed testing and the calibration and maintenance of the test equipment, in order to allow the VB to determine their adequacy (see appendix 7 of the GVP for the complete list of such items). The GVP also says that:

> *"The accepted existing data are summarized in the format to be used when reporting test data."* (B.IV.5)

This means that existing data should be summarised and presented in the same format as required from new data. Finally it also stems from the GVP (B.IV.5) and (C.II) that raw data must be available, as well a description of the test methods, and the documentation related to the quality management of the data (e.g. quality control data).

3.4 Acceptable deviations

It is important that the test report describes any deviations to the Specific Verification protocol, the test plan, the test methods and QA procedures of the test body. These deviations have to be judged acceptable by the VB in order to enable the acceptance of existing data.

3.5 Evaluation of the test and quality management systems

As indicated above, without an ISO/IEC 17025 accreditation valid at the moment of the testing covering the tests under consideration, then test system assessment has to include a "test system audit". The test system audit is meant to help the VB in evaluating the suitability of the quality management and the test systems[6].

Here are the circumstances under which it is considered justified not to perform the 'test system audit' for existing data:

a. At the time of testing, the test body was ISO / IEC 17025 accredited for the methods of testing and calibration relevant for the verification process

b. At the time of testing, the test body was ISO / IEC 17025 accredited for tests that are very similar to those involved in the verification process, in that they provide data of the same quality.

c. When the VB has positively audited the test body for identical or very similar tests, within a period of 12 months before or after the tests, and has sufficient confidence in the quality of the test system for the tests at hand.

It has to be noted that this audit may be more complicated to perform and may be less conclusive than for existing data. Auditing the current situation would not reflect the situation that prevailed when the existing data were generated. Therefore the VB has to consult the archives of the test body to find out what situation prevailed at that time, which may be a difficult and time consuming task. The older the test data are the more likely it is that the situation of the test body will have changed (new personnel, new procedures, new equipment….), which may limit the relevance of the on-site findings. However, old data with very good quality

[6] The test system is the system in which the test data have been produced. It covers calibration of instruments, sampling procedures, record keeping, data management, etc. i.e. topics covered by chapter 5 of ISO 17025

records could still be considered as valid (risk-based assessment). This makes putting a defined time limit on the acceptance of existing data impractical, so it must be left to the VB, in consultation with external experts if necessary, to determine what an acceptable time limit is.

A good practice would be that the proposer anticipatively invites the VB to perform a test system audit before or during the tests (i.e. before the start of the verification and in the context of a specific contractual arrangement). The VB could then use the collected information during the verification process (see witness check below).

When the test system does not exist anymore (e.g. test facilities have been dismantled), the audit shall include at least an in-depth desk review of the test body QA documentation related to tests performed, in force at the time of testing. Whenever possible and relevant, the desk review shall be accompanied by on site observations performed at the place of testing.

The above mentioned QA documentation is made of procedures and records (staff training and qualification, calibration of instruments, measurement and data logs, tractability sheets, non-conformities, test methods and method validation reports…). If such documentation is not available or not suitable/sufficient, the data cannot be accepted.

The audit should also examine the reliability of the tests by reviewing past records documenting the reliability of the data produced by the test body (e.g., laboratory control data for relevant period, evaluation of data from laboratory participation in proficiency test and control of calibration of online measurement devices,…).

Since the audit is similar for both new and existing data, the specific guidance document related to auditing of test bodies should be used[7].

The core point is that the VB possesses sufficient evidence to be confident that the tests have been carried out properly and in line with requirements of the GVP, the specific verification protocol and the test plan, e.g. by qualified personnel, using adequate and properly calibrated instruments, following appropriate methods, using suitable sampling and data management procedures etc.

The results of this assessment are reported in section 5 of the Verification Report and of the Verification Statement.

If possible and relevant, the test system audit may be performed before the finalisation of the specific verification protocol, so that a greater level of confidence in the acceptance of existing data can be reached.

3.6 Appropriate Test methods

The test data shall be collected using robust and appropriate test methods and sampling/reporting procedures in order to make sure that the figures correctly reflect the parameters to be assessed. The test method shall be in line with the requirements of the Specific verification protocol.

The GVP (B.IV.4) specifies that:

[7] TWG Guidance_009 - Auditing of test bodies under preparation at the time of adopting this document.

> *"If available and relevant, existing standard methods (e.g. ISO, CEN) should be used. Where no standard methods exist, documented methods shall be required and/or clearly described in the specific verification protocol or reference made to publicly available documents such as peer reviewed scientific articles."*

In cases where the existing data have been produced using non-standard methods, the documented evidence supporting the(se) method(s) shall be provided. The VB shall evaluate the suitability of the method, paying special attention to elements including: method validation, skills, traceability etc. (see also ISO / IEC 17025 section 5.4). This evaluation may include consultation with relevant test laboratories while respecting the necessary confidentiality requirements. The result of this evaluation shall be documented in Section 6.2 of the Specific Verification Protocol.

3.7 Final evaluation of existing test data

As indicated earlier, the data and accompanying documentation must be sufficient and provided in the appropriate format in order to allow this evaluation.

Meeting the requirements of the Specific Verification Protocol is an essential requirement. Deviations to the Specific Verification Protocol have to be reported and evaluated. Deviations that are not judged acceptable to the verification body shall lead to the rejection of the data, possibly after a dialogue with the proposer. This requirement is not discussed further here, because it derives directly from the Specific Verification Protocol, which should provide the method or criteria for evaluating the compliance of data with requirements.

Besides the Specific Verification Protocol requirements, the Verification Body should have a critical look at the existing data, examining in particular whether the data are:

- reliable, i.e. collected using appropriate methods and procedures (see 3.6) and within an appropriate quality system (see 3.,1 3.2 and 3.5)
- of sufficient quality, e.g. within the sufficient level of precision,
- relevant to the technology, i.e. related to the current version of the technology (and not to an outdated version), but also reflecting adequately the verification parameters set out in the SVP,
- relevant to test scale, e.g. collected at the same technical scale as the intended technology
- relevant to feed material, e.g. collected from tests with similar feed material
- complete, i.e. covering all the relevant parameters including environmental and performance parameters. (NB: incomplete existing data does not necessarily have to be rejected, provided it can be complemented by new data).

If an important parameter is missing from the data sets, the existing data may have to be rejected. For instance if ambient temperature influences the performance of an energy saving device, but ambient temperature was not monitored during testing, then the data should not be used for the verification, or only with extreme caution and with the necessary caveats in the verification report and verification statement.

A statistical analysis has to be performed in order to determine the validity of the results, e.g. are the standard deviation and confidence intervals within acceptable limits, are there outliers etc.? In

principle adequate acceptance criteria should have been developed in the Specific Verification Protocol. A separate guidance document addresses the statistical evaluation of the results[8].

All the relevant new and existing data that have been collected have to be presented and discussed. Partial or selective elimination of data is not allowed unless there is a good reason for doing so, e.g. in the case of outliers that can be attributed to experimental errors. When such a situation occurs, this shall be acknowledged and duly justified in the Test and Verification reports and, if potentially impacting the conclusions of the verification, in the Verification Statement.

The 'tools' presented in section 4 allow deeper insight in the acceptability of the existing data. To the extent possible, their eventual usage should be anticipated in the Specific Verification Protocol.

4 Evaluation 'tools'

In chapter C.II of the GVP, a series of 'tools' are suggested in order to get more insight on the reliability, quality, completeness and relevance of existing data. The eventual use of these 'tools' should be, whenever possible, indicated in advance in the Specific Verification Protocol. These tools are recommended by the GVP "*in particular in the absence of accreditation or in the case of data produced by the proposer or by bodies dependent upon the proposer*" (C.II).

When they are used, their outcome should be documented in the verification report. These tools are presented and discussed below, with a summary table at the end:

4.1 Spot checks

The terms 'spot check' refer to the random checking of a certain portion of the data. For example it can be considered advisable that between 5-10% of the existing data for each claim is checked[9]. The checks should concern all the steps where the introduction of an error is possible. It can be for example the transcription of raw data into a spreadsheet, or the statistical calculations and interpolations carried out by the test body.

If a mistake is identified, its origin should be investigated and, when possible, the values should be corrected. In this situation, a broader range of data should be checked in order to detect other possible mistakes. Eventually, a complete check may be needed in cases where several mistakes are identified.

Correction of mistakes can only be done once their source is identified and one is sure that the corrected dataset adequately reflects the situation. Such corrections have to be reported in the Specific Verification Protocol or in the verification report where applicable.

If errors cannot be corrected satisfactorily, or if the errors cast doubt on the reliability of the data, then the existing data should be rejected, partially or totally. However errors that will not influence the conclusion of the whole verification can be tolerated but should be reported

[8] Under preparation at the time of adopting this document.

[9] A statistical risk perspective might help to decide an appropriate proportion or amount of data.

anyway, with the reason for accepting them. For example, let's assume that there is doubt whether the value of 1 sample out of 50 samples is 782,8 or 788,8. The impact of the error on the value of that particular sample is less than 1% and the impact on the average value of all samples is less than 0,015 %. If the required precision for this particular test is 1%, the error can be tolerated.

4.2 Witness checks

This covers several possibilities:

A) A visit to the test body's premises and evaluate 'quantitatively' the 'performance' of the tests. Typically this would involve repeating some tests using the same methods and procedures as for the existing data and see whether any significant difference arise. Samples with known properties could be tested in order to determine the accuracy of the measurement chain (e.g. actual detection limit and precision). The checks may focus on the measurement devices that have been used in order to determine the repeatability and accuracy of the results.

B) Alternatively, this may refer to the witnessing by the VB of the tests performed before the start of the verification, while respecting the conditions of independence between VB, proposer and test body. The observations (e.g. evidence that quality assurance and testing procedures have been respected and possible deviations) made by the VB on this occasion would then be included in the elements used by the VB to evaluate the existing data (to be reported in section 6.2 of the Specific Verification Protocol).

4.3 Conditional acceptance of existing data

Conditional acceptance of existing data is a powerful tool to ensure suitability of the existing data. Typically, conditional acceptance may be linked to additional testing confirming the existing data or to the execution of the test system audit. When the new tests show significant differences with the existing data, the reasons need to be investigated and, when applicable, the existing data should be rejected. This leads to an iterative verification process, as described in section 2.4 above.

Conditional acceptance may also be linked to the successful outcome of the spot checks, the witness checks, and/or the test system audit mentioned above. If case the test system audit is required by the GVP but could not be carried out before the finalisation of the specific verification protocol then conditional acceptance of the existing data is necessary.

In the case of conditional acceptance, this provisional conclusion about the acceptance of existing data should be reported in the Specific Verification Protocol, section 6.3, with the conditions attached to the acceptance explicitly and clearly mentioned. The conclusion on the possible need for further tests, in Section 6.4 of the Specific Verification Protocol, should logically be also conditional. The final conclusion on the acceptance of existing data should in this case be reported in the verification report, Section 3.1, together with the results of spot checks, witness checks and/or test system audit where relevant and any other check or assessment of the existing data undertaken after the Specific Verification Protocol stage.

In principle, the acceptance should remain conditional until the VB has examined all evidence supplied by the proposer, gathered all elements needed to perform the verification, including results from any tests, checks and audits, and has made sure that all requirements related to existing data are met, i.e. in most cases until the verification report is finalised and approved.

4.4 Summary table and recommended use

Here is a more detailed recommendation for the use of the 'tools' presented above:

Type of 'tool'	**Recommended use**
Spot check	In all cases where an exhaustive check is not possible or appropriate
Witness check	In the absence of accreditation, and/or in case of data reliability concerns, and/or in the case of data produced by the proposer or by bodies dependent upon the proposer (e.g. in house testing)
Conditional acceptance	In the absence of accreditation, and/or in case of data reliability concerns, and in conjunction with one of the 2 items above.[10]

[10] Keeping in mind that the final and definitive acceptation of the existing data occurs at the verification report stage, as indicated above.

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